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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Suite 200
Maitland, FL 32751

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Warning Letter

FLA-05-19

February 22, 2005

Mr. Ian Ramsay, President
Alva Jade Enterprises, Inc.
6818 NW 20th Avenue
Ft. Lauderdale, FL 33309

Dear Mr. Ramsay:

On November 4, 2004, FDA Investigator Sherbet Samuels inspected your firm at 6818 NW 20th Avenue, Fort Lauderdale, Florida. During the inspection, the investigator collected labeling for two products you manufacture and offer for sale, namely, Varisi The Formula for Clean and Healthy Nails, and Varisi Healthy Feet. We have also reviewed your Internet web site at the following address: http://www.varisi.com. Our review reveals that your products are being marketed in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and its implementing regulations on our Internet web site at www.fda.gov.

Under Section 201(g)(1)(B) of the Act (21 U.S.C. 321(g)), articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs. The following claims on your products' labeling, including promotional materials entitled "Restore Problem Nails Healthy Feet" and "Restore Problem Nails" indicates that your products are intended to be used as drugs:

Varisi Healthy Feet

- "Use for Dry Peeling Skin, Itching Toes, Thick Cracking Callouses (sic)." "Varisi Healthy Feet...has been specially designed for skin conditions including thick heavy callouses (sic) around the heel of the foot that show dry, white powdery skin between the cracks of the callous (sic). Burning itching toes and dry peeling skin. Look for positive results within seven days."

Varisi The Formula for Clean and Healthy Nails

- "Restore Problem Nails." "It Works." Product label depicts pictures of diseased and distressed finger and toe nails.

- Under "Frequently Asked Questions," "Q. Then it's o.k. for fungus to grow under finger and toe nails, because its (sic) fulfilling a purpose?" "A. Certainly not. As nail technicians, fungus growing under and on finger and toe nails..."

Intended use as a drug from website

Moreover, your promotional literature for Varisi The Formula for Clean and Healthy Nails also directs the reader to your website http://www.varisi.com where this product's intended use is further established by referencing nail disorders, pictorial depictions of diseased nails, and the product's claimed ability to "exert a positive influence on nails that have been adversely affected by trauma..." Your website lists five types of traumas (i.e., chemical trauma, acute trauma, micro trauma, mechanical trauma, and non-traumatic diseases).

Antifungal

Furthermore, the following promotional claims for Varisi Healthy Feet appeared on your website at http://www.varisi.com:

- "Thick heavy callous (sic) around the heel of the food that show dry, white powdery skin between the cracks of the callous (sic), surrounded by small white broken blisters." "This condition is often confused with excessive dry skin, when it is (sic) fact a common skin fungus." "This fungus can be transmitted from one person to another and is very prevalent in gymnasiums." "Use on all bacteria & skin fungus conditions including athletes (sic) foot." "Look for positive results in seven days"

New Drugs

Because the products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in Section 201(p) of the Act (21 U.S.C. 321 (p)). New drugs may not be legally marketed in the United States without prior approval from FDA as described in Section 505(a) of the Act (21 U.S.C. 355(a)).

OTC Monograph

The antifungal claims further document your product's intended use (i.e., to treat athlete's foot) as a drug as defined in Section 201(g)(1)(B) of the Act. Thus, in the absence of an approved new drug application under Section 505 of the Act, the product is subject to final regulations covering topical OTC antifungal drug products (21 CFR Part 333, Subpart C). Consequently, the product is misbranded under sections 502(e) and 502(f)(1) and (2) of the Act in that the product fails to bear a statement of identity, directions for use, and warnings as required by 21 CFR 333.250(a)-(d).

In addition, the product Varisi Healthy Feet is misbranded under section 502(c) of the Act in that the labeling of Varisi Healthy Feet fails to comply with the regulation covering the format and content of OTC drug labeling (21 CFR 201.66).

This letter is not an all-inclusive review of your promotional labeling, including your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against the manufacturers and distributors of those products. You should take prompt action to correct any violations identified in this letter. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing and within fifteen (15) working days of receipt of this letter, as to the specific steps that you have taken to correct any violations and to assure that similar violations do not occur. If corrective action cannot be completed with fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be addressed to Shari H. Shambaugh, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely,

Emma R. Singleton
Director, Florida District